Discussion

The setting of this study was an Indian referral and teaching hospital which is typical of more than 100 such hospitals across the country. The study encompassed the breath of the problem of nosocomial infections in the hospital describing the epidemiology of two major groups of nosocomial pathogens (\textit{S. aureus} and species of Enterobacteriaceae) in terms of resistance to antimicrobials and identified the main drivers of spread of these pathogens \textit{viz.}, selection pressure exerted by specific antimicrobials in use and uncontrolled crosstransmissions. The study concludes that the exposure to specific antimicrobials probably play the most important role in terms of patients acquiring resistant pathogens as evident from the fact that the duration of stay in absence of antimicrobial exposure is not a risk factor for acquisition of multiresistant nosocomial pathogens. This conclusion is based on the assumption that the longer a patient stays in the hospital the chances of exposure to nosocomial pathogens increases (more so in absence of specific infection control measures such as high standard of hand hygiene) which should have led to acquisition.

This study describes the point prevalence of antibiotic resistance in \textit{S. aureus} and species of Enterobacteriaceae \textit{vis-à-vis} risk factors particularly in reference exposure to and usage of specific antimicrobials. The study characterises the prevalent MRSA strain using antibiogram, phage and RFLP typing shedding light on probable genotype of the strain in the hospital.

The study confirms the anecdotal observation that there was no formal hospital infection control programme in the hospital, and no or a few specific infection control interventions were in practice during the study period. The routine clinical microbiology service was limited and antibiotic therapy was empirical based on prescriber’s experience and clinical judgment.
However, the study had certain limitations. This was a point prevalence study designed to determine only the rate and risk factors for colonisation rather than infections (and its severity) which is the most important outcome measure. In this sense this study is a precursor to more in-depth studies on HCAIs in this hospital to describe not only local epidemiology of resistance but also rate, outcome and associated cost of HCAIs and appropriate cost-effective intervention strategies.

Nevertheless, the study revealed the widespread presence of a predominant multiresistant strain of MRSA and multiple species of ESBL-producing Enterobacteriaceae. Extensive crosstransmission of these pathogens was observed, which was not surprising given that there were no or little specific infection control interventions in the hospital. Further, it is clearly demonstrated that the empirical antibiotic therapy against any HCAIs caused by any of these pathogens was ineffective. These antimicrobials were contributing to the spread of multiresistant nosocomial pathogens rather than effectively treating any infections potentially caused by these pathogens.

Further in-depth studies on specific aspects of HCAIs in the hospital such as rate of different categories of HCAIs and its consequences, and, importantly, identifying feasible and cost-effective interventions are required. In addition, further molecular characterisation of these pathogens, particularly the characterisation of ESBL, would add to the knowledge of local epidemiology which is inadequate at the moment.

In the following section a few specific results of the study are discussed in more detail.

**Rate of colonisation**

Given that there were no or a few infection control interventions, the rate of MRSA colonisation of 34% and 18% in orthopaedics and surgery, respectively, and only ~1% in medicine was somewhat lower than expected. It could be partly due to dry swabs used and not using an enrichment technique. Direct plating of MRSA swab on to MSA plate has a
sensitivity of 79% compared to the most sensitive conventional culture methods of broth enrichment followed by plating on MSA containing lipovitellin and an oxacillin disk (MSALox). The colonisation rate of MRSA found in this study was therefore an underestimate by at least 21%. The reason for the high prevalence of MRSA in orthopaedic compared to surgery was likely to be the higher rate of cross-transmissions attributable to overcrowded nature of the unit (100% bed occupancy with provisions of two extra beds made on the floor).

**Usage of antimicrobials**

Overall consumption antimicrobials for systemic use were 92.6, 59.9 and 53.3 DDD/100 bed days in the surgical, orthopaedic and medical units, respectively. Consumption of cephalosporins and aminoglycosides were similar across the specialities (22-29 and 8-12 DDD/100 bed-days, respectively) but fluoroquinolone consumption was disproportionately higher in surgery, 41 as opposed to only 7-8 DDD/100 bed-days in orthopaedic and medicine. The third generation cephalosporins, fluoroquinolone and aminoglycosides constituted the bulk of the total consumption.

There is no published study on antimicrobial consumptions in Indian hospital to compare data from the present study. There are few published international studies on volume and pattern of antimicrobial consumption but no benchmark exists as to the appropriate volume of consumption in a specific type of hospital. One study from 40 non-University regional general hospitals (medicine, non ICU) in Germany in 2001-02 found mean consumption 49.9 (ranges from 13.5 and 93.7 DDD/100), whereas a second study from 145 acute German hospitals in 2003 found mean consumption of 49.6 DDD/100 bed-days. These data are comparable to average consumption found in medicine in our present study (53 DDD/100 bed-days). In general, the consumptions seem to vary across the locations, the ‘acute’ wards consuming higher volume. The ICU antibiotic usage of antimicrobial
was much higher; use in haematology-oncology was higher than in other non-surgical departments/wards and in multivariate analyses university affiliation and haematology-oncology were found to be independently associated with comparatively high use\textsuperscript{315}.

Our own audit data from a DGH in England showed that the total consumptions in medical wards was average 53 DDD/100 bed-days (range 20 to 114 DDD/100), which is again comparable with the consumption in medicine in our study hospital. Penicillins, which includes anti-staphylococcal and anti-pseudomonal penicillins, were the highest consumed group of antibiotics followed by macrolides and quinolone in this English hospital, which is in sharp contrast to the situation in our study hospital where consumption of penicillins was very low (7-15 DDD/100 bed-days).

However, the total consumption of antimicrobials in surgery (93 DDD/100 bed-days) was found to be very high comparable only with the volume of consumption in adult Intensive Care Unit (ICU) in the US (83 DDD/100 bed-days)\textsuperscript{316}. Our audit from the English DGH showed significantly lower consumption in the surgical ward audited (68 DDD/100 bed-days). This unusually high volume of consumption in surgery in the present study indirectly was suggestive high SSI rates and also reflected in high rate of colonisation rate with ESBL-producing organisms.

In summary, the total volume of consumption of antimicrobial in medicine was comparable to hospitals in the developed countries, whereas consumption in surgery was significantly higher followed closely by orthopaedics.

The pattern of usage of these antimicrobials also demonstrated inappropriate usage in the sense that none of the antimicrobials used in the hospital was effective against instances of HCAIs potentially caused by MRSA and/or ESBL-producing species of Enterobacteriaceae. Any infections potentially caused by these bacteria were virtually left untreated; contribution of antibiotic therapy was in fact nil even in those who might have recovered from such infections. Similarly, patients admitted with community acquired
infections caused by MSSA (e.g., most skin and soft tissue infections) or early SSI would have been most appropriately treated with inexpensive anti-staphylococcal penicillins like cloxacillin or erythromycin rather than third generation cephalosporins. Likewise, community infections caused by species of Enterobacteriaceae (e.g., uncomplicated cystitis) could have been treated by cheaper and yet effective older antibiotics rather than quinolones or third generation cephalosporins.

These findings reflect arbitrary nature of empirical antimicrobial prescription in the hospital, an inevitable consequence of lack of awareness of antimicrobial susceptibility of the common locally prevalent nosocomial pathogens.

**Origin of the multiresistant strains in the hospital**

This study cannot speculate on the origin of circulating strain of MRSA i.e., how it was first introduced to the hospital, or of ESBL producing strains, but there is no uncertainty that the inappropriate empirical usage of certain antimicrobial classes and uncontrolled cross-transmissions are perpetually driving the spread and acquisition of drug-resistant bacteria by the patients admitted to the hospital and potentially helping spread to the community.

**MRSA**

The phage typing confirmed by PFGE typing of the representative strains showed the presence of one predominant MRSA strain across the units confirming the role of cross-transmissions and inadequate infection control practices.

The typical antibiogram-resistogram of the MRSA strain and tight co-relation of resistance to certain antimicrobials are almost conclusive of the presence of SCC<sub>mev</sub> type either II or III (See Resistance to other antibiotics, on page 43). The MRSA strain phenotypically resembles (and probably evolutionarily related to) the predominant Asian strain viz., Brazilian/Hungarian strain (CC8-MRSA-III) which is the major clone in Asian countries.
including India, except Korea and Japan (See Distribution of major genotypes of MRSA clones in Asia on page 43).

Coagulase Negative Staphylococci (CoNS)

We did not speciate CoNS, a group of at least 30 individual species; about half of these are indigenous to humans, which usually colonise skin and mucous membranes surrounding openings to the body surface. The CoNS are of increasing in importance as causes of hospital-acquired infections, particularly infections of prosthetic and indwelling intravascular devices, and the proportion of nosocomial CoNS resistant to meticillin is increasing; widespread skin colonisation also serves as a potential reservoir for multiresistant isolates that cause infections.

ESBL producing Enterobacteriaceae

We did not type ESBL producing species. Although, *E. coli* (n=17) and *K. pneumoniae* (n=30) dominated, multiple species (*C. freundii, E. aerogenes, E. cloacae, M. morganii, P. mirabilis and P. vulgaris*) with different antibiogram-resistogram within a single species were prevalent in the hospital. A few of ESBL producing *C. freundii* and enterobacter species were also found to be AmpC derepressed mutants.

In the current study, ESBL producing species of Enterobacteriaceae were consistently resistant to ciprofloxacin, gentamicin, tobramycin and netilmicin (P <0.001) even though tobramycin and netilmicin were not in use in the hospital suggesting presence of an R-plasmids and 'associated linkage selection' by exposure to ciprofloxacin and gentamicin. Conjugative R-plasmids usually carrying genes for resistance to more than one antibiotic class are able to maintain themselves by infectious transfer within the gram negative bacterial population even without any selection pressure. Also, antibiotic mediated associated linkage selection maintains resistance to antibiotics that are not in use for long time. In contrast, only 18% of ESBL producers were resistant to amikacin; 5% of the non-
ESBL producing isolates were also resistant to amikacin and the difference was not statistically significant (P >0.1) suggesting independent acquisition of amikacin resistance determinant by species of Enterobacteriaceae. All ESBL producing organisms were susceptible to meropenem, and only to colistin among the non-β-lactam antibiotics tested. In addition, 50% were sensitive to cotrimoxazole and chloramphenicol.

The possibility of the presence of CTX-M ESBL amongst the ESBL producing isolates was considered. Classical CTX-M enzyme was not detected given that all ESBL isolates were consistently resistant to both cefotaxime and ceftazidime. There were at least 11 (four E. coli, six K. pneumoniae and one E. cloacae) isolates that had no zone diameter to cefotaxime but 10-17 mm zone size to ceftazidime. In addition, there was one K. pneumoniae isolate with zone size diameter 19 mm to ceftazidime with none zone to cefotaxime. By BSAC interpretation the zone sizes ≤ 17 mm is resistant and 18-29 mm (corresponding to MIC 2-8 mg/L) is intermediate. These zone diameter imply extremely high MIC to cefotaxime (reflected by no diameter) but comparatively lower MIC to ceftazidime (still within the resistant or intermediate category). We did not find any isolate with no zone diameter to both cefotaxime and ceftazidime. These phenotypic observations do not fit with CTX-M-15 either, a variant of the CTX-M-3 enzyme, which has very high MIC (mg/L) >256 and >512 conferring frank resistance to both ceftazidime and cefotaxime, respectively, which appears to be the predominant variant isolated in India so far.

The epidemiology of ESBL could be complex in a hospital which can be fully described by molecular study of the specific ESBL involved and plasmid analysis e.g., whether a single plasmid is disseminating in genotypically unrelated strains of a single or different species, or multiple plasmids carrying different ESBL genes are prevalent in different strains or even within a single epidemic strain. Also, same ESBL may be mediated by different
plasmids. The effects of antibiotic pressure or plasmid transfer from organism to organism may drive independent evolution of ESBL producing Enterobacteriaceae species.

Risk factors

Among other risk factors, exposure to the aminoglycosides (mainly gentamicin) turned out to be very strongly associated with acquiring ESBL producing Enterobacteriaceae but not MRSA despite the fact that both MRSA and ESBL producers were consistently resistant to gentamicin. Gentamicin dosing in use in this hospital was multiple as opposed to the now standard ‘once daily’ regimen, and often given in small and infrequent doses (typically 80 mg BD). Also, exposure to cephalosporins was a risk factor for acquisition of ESBL-producing Enterobacteriaceae only.

Exposure to fluoroquinolone (ciprofloxacin) was a risk factor for MRSA but not for ESBL-producing Enterobacteriaceae even though both were resistant to ciprofloxacin. Ciprofloxacin usage was associated with selection of MRSA in other studies which is consistent with our results\textsuperscript{321, 322}.

Surgery is the only common risk factor for independent acquisition of MRSA and ESBL producing Enterobacteriaceae. This is probably because majority of the surgical patients were likely to be exposed to high risk antimicrobials associated with acquisition of MRSA (ciprofloxacin) and ESBL producing Enterobacteriaceae (cephalosporins and aminoglycosides).

Duration of hospital stay was not found to be a risk factor for neither MRSA nor ESBL-producing Enterobacteriaceae colonization in this study. This was despite the fact that almost all MRSA and ESBL-producing Enterobacteriaceae were hospital acquired and yet a vast majority of patients remained free from acquiring these pathogens implying that even uncontrolled cross-transmission alone is not sufficient for acquisition of resistant organisms in absence of other risk factors, particularly exposure to high risk antimicrobials. This
finding underlines the importance of colonisation resistance offered by the commensals against the nosocomial pathogen and that the exposure to antimicrobials causes serious dent to this innate defence against external pathogens.

**Antimicrobial resistance profile**

The antimicrobial resistance profiles of MRSA strains circulating in the hospital was alarming; all were uniformly resistant to erythromycin, ciprofloxacin, trimethoprim, gentamicin and tobramycin, and 96% were also resistant to clindamycin, cotrimoxazole, amikacin, netilmicin and neomycin. Resistance to chloramphenicol (MRSA 56%; MSSA 44%) and rifampicin (MRSA 15%; MSSA 44%) did not show any correlation with meticillin sensitivity. We have not tested linezolid but isolates are unlikely to be resistant as linezolid was not been introduced in India at the time of the study. All MRSA were susceptible to synercid, vancomycin, teicoplanin and 96% to fusidic acid. In contrast, the meticillin sensitive isolates were more likely to be sensitive to these antimicrobials (P < 0.001).

We found 47% of CoNS were resistant to meticillin and majority (79%) of these from the patient with ≥ 72 hours hospital stay. 46% of the meticillin resistant CoNS had erythromycin, ciprofloxacin trimethoprim, and gentamicin and tobramycin resistance profile, a profile similar to the predominant MRSA clone. It is possible that these CoNS isolates carry the same SCCmec element as MRSA strain which can only be conclusively established by SCCmec typing.

Significantly, resistance among the non-ESBL-producing Enterobacteriaceae was not very high except to ampicillin. About three-quarters of all isolates (both community and hospital) were resistant to ampicillin followed by cephalexin (17% community and 32% hospital) with no resistance detected against cefuroxime and third generation cephalosporins. Despite high consumption, 95% of all hospital isolates were sensitive to
ciprofloxacin. Similarly, 89% and 79% hospital isolates were sensitive to cotrimoxazole and trimethoprim, respectively with no resistance detected in community isolates. This may be related to the fact that over the last several years usage of these two drugs may have significantly fallen even in the community due to perceived resistance. However, resistance to chloramphenicol remains moderately high (25%-32%) despite decreasing use. These non-ESBL isolates are also highly sensitive to gentamicin (95%-100%), amikacin (100%) and tobramycin (89%-100%). However, netilmicin sensitivity is only 47% and 83% among hospital and community isolates, respectively.

With no routine diagnostic microbiology services, blind empirical treatment was not effectively treating these resistant organisms. Given the nature of the case mix it is conceivable that ESBL-producing organisms are mere colonisers in majority of the cases and only infrequent cause of sepsis. But the same cannot be said for MRSA, which is a primary pathogen. Although, our study was not designed to detect the rate of surgical site infections (SSI), it is highly likely that MRSA was responsible for a major proportion of SSI.

In foreseeable future with more intensive management becoming available the scenario is going to change with colonisation leading to high rate of infections, particularly life threatening gram-negative sepsis, caused by resistant organisms. Therefore, role of cost-effective microbiology services appropriate for developing countries are urgently required to meet the challenge. Simple interventions like improved hand-hygiene are likely to go a long way in controlling cross-transmissions; recent promotion of alcohol based sink-less hand rubs by the WHO is a way forward for developing countries.

The selection pressure exerted by specific antimicrobials and cross-transmissions are undoubtedly the two main forces driving antimicrobial resistance in hospitals. But host factors such as immune status, co-morbidities, nature of the bacterial species, and therapeutic interventions are equally important, which are often not quantifiable, for
resistant pathogens to establish itself in the milieu of complex microbial flora of the host. Studies are necessary to define and quantify these additional factors in hospitals of the developing countries which are different to the hospitals in the developed countries as shown in our study. Mathematical modelling is ways forward to answer many questions of this complex dynamics but even then valid parameters have to be obtained from clinical studies. Overall, there is need for more innovative epidemiological and experimental research in the clinical environment of developing countries.

In conclusion, the results of this study highlights an opportunity to sequentially introduce simple but specific infection control interventions such as hand hygiene or clinical guidelines for usage of antimicrobial to treat infections and prophylaxis, and evaluate the effectiveness of each specific intervention, which is not feasible to carry out in developed countries where multiple and complex infection control and antibiotic prescribing interventions are already in place. There is a need to determine the efficacy of specific intervention so that resource is not wasted on intervention which is not cost effective.

**Recommendations**

In the light of the findings of this study and current experience from the developed world, certain measures both immediate and medium term to develop a framework for ensuring safer care minimising the risk of avoidable HCAIs are recommended in this section.

The proportion of nosocomial infections potentially preventable under routine working conditions remains unclear but studies showed that a significant proportion can be prevented. The 1985 landmark SENIC study \(^{325}\) showed that with intensive infection control and surveillance programmes an overall reduction of 32% in nosocomial infection rates could be obtained in a five-year period. A more recent review of 30 multi-modal intervention studies and studies assessing exogenous cross-infection, found a minimum reduction effect of 10% to a maximum effect of 70%, depending on the setting, study
design, baseline infection rates and type of infection\textsuperscript{326}. The authors concluded that on average 20–30\% of all nosocomial infections occurring under current healthcare conditions can be prevented. An even larger proportion (\textgreater{}50 \%) of device-associated bloodstream infections seems to be avoidable, with studies investigating multi-modal interventions reporting reductions in catheter-related bloodstream infections ranging from 29\% to 95\%.\textsuperscript{327, 328} As for ventilator-associated pneumonia, studies suggest that average reductions of more than 40 \% are possible\textsuperscript{329}.

Over the last few years, the rate HCAIs has emerged as one of the leading markers of quality of clinical care and patient safety. Reducing the rate of HCAIs requires investment to renovate the existing built environment to ‘design in’ certain provisions for infection control but not itself sufficient to achieve the best possible results. To make continuous improvement it is essential to make changes the way the system works. However, driving changes and making improvement in a complex organisation like a hospital is a challenging task, particularly when it comes to a problem like HCAIs where change in attitude and behaviour by the medical and nursing staff is as critical as available facilities and resources dictating success or failure. Infection control in developing countries is difficult not always because of resources but because it is not seen as a priority due to lack of awareness hindering development of necessary framework and approach.

Lack of awareness is a direct consequence of lack of measurement and availability of surveillance data on HCAIs at local level. Although, surgical site infections, urinary tract, infections, hospital acquired pneumonia including ventilator associated pneumonia and intra-venous device associated infections are of common occurrence, often with serious consequences (severe sepsis and septic shock) contributing to morality and morbidity, clinicians come to accept these as unavoidable consequence. Lack of institutional framework or programme to deal with HCAIs perpetuates the culture of acceptance of HCAIs as inevitable. That most HCAIs are avoidable and can be prevented by relatively
simple means can only be appreciated by measuring the local rate, putting interventions, which are often simple, in place and then remeasuring the rate to see the difference.

Inadequate microbiology laboratory services and lack of clinical microbiology expertise are also problems. That the incidence of infections with multi-resistant nosocomial pathogens such as MRSA or ESBL producing enteric gram negative bacteria are high require microbiological confirmation.

Infection control and prevention is not isolated from improving care and safety in general. A safer clinical care environment and adherence to basic principles address many issues related to infection control. In this respect, however, it is learnt from the recent experience in the developed countries that it is important that infection control is accepted as a core corporate and individual responsibility by the management and clinical staff, respectively facilitated by an infection control team (ICT) and a programme to achieve and sustain low HCAI rate. It is also necessary that the effort to combat HCAIs is whole heartedly backed by the government including putting in place legislative framework making infection control a priority and core responsibility of the top level hospital management. In England safeguarding patients and staff from the risk of avoidable HCAIs is made a statutory responsibility of the hospital management.

**Improving the system**

While investment in infrastructure and equipments are essential to provide improved patient care and lower the risk of harm, this alone is not sufficient to sustain the benefits achieved as a result of capital investment. There has to be continuous effort to make incremental improvement of the service provided within the available resources and constraints. Reducing incidence of HCAIs is considered now an integral part of patient safety and quality of care. As such, the hospital needs to embark on a planned ‘quality
improvement programme’ incorporating reducing HCAI and ensuring safe surgery as primary objectives.

**Improvement Method**

Any improvement process should be driven by leadership, with a commitment to providing adequate resources and attention to the initiative. It is also imperative to involve a multidisciplinary team. Successful teams set clear aims for their work, establish baseline measurements, regularly measure and study the results of their work, and test various process and systems changes over a variety of conditions in order to find the ones that lead to improvement in their particular setting.

The Model for Improvement\(^{333, 334, 335}\) developed by Associates in Process Improvement\(^{336}\) is a simple yet powerful tool for accelerating improvement. This model has been used very successfully by hundreds of health care organizations in many countries to improve many different health care processes and outcomes.

The model has two parts:

Three fundamental questions (which can be addressed in any order):

1. What we are trying to accomplish? This requires setting aims. The aim should be time-specific and measurable; it should also define the specific population of patients that will be affected.

2. How will we know a change is an improvement? This requires establishing base line measures. Teams use quantitative measures to determine if a specific change actually leads to an improvement.
3. What changes can we make that will result in improvement? This requires selecting changes. All improvement requires making changes, but not all changes result in improvement. Organizations therefore must identify the changes that are most likely to result in improvement.

Plan-Do-Study-Act (PDSA) cycle is to test and implement changes in real work settings on a small scale\textsuperscript{337}. The PDSA cycle guides the test of a change to determine if the change is an improvement.

**Forming the team**

Including the right people on a process improvement team is critical to a successful improvement effort. Teams vary in size and composition. Each organization builds teams to suit its own needs\textsuperscript{338}. Effective teams include members representing three different kinds of expertise within the organisation: system leadership, technical expertise, and day-to-day leadership. There may be one or more individuals on the team with each kind of expertise, or one individual may have expertise in more than one area, but all three areas should be represented in order to drive improvement successfully.

It is necessary that that the hospital forms a steering group (could be called Care Improvement Council) involving the senior administrator, doctors and nurses. The authority should entrust the group to drive a range of improvement programmes from immediate pressing needs like reducing HCAIs, improving surgical safety and implementation of antimicrobial guidelines to strategic objectives like reducing hospital stay and bed-occupancy which positively impact on rate of HCAIs.
Care Improvement Council: Principal cum Chief Superintendent (Chair), Superintendent (Secretary), Head of the Departments, senior matrons, senior faculty members, representatives of service agencies, public representative, technical experts.

Project teams: Comprises of a team leader, technical experts and day-to-day leaders at the ground level. The specific composition of the Infection Control Team (ICT) is outlined in the next section.

The senior management and doctors would find it useful to use of the Web-Based Learning modules on the "How To" of Improvement developed by the Healthcare Improvement Skills Centre (www.improvementskills.org) in partnership with Institute Healthcare Improvement (www.ihi.org). These modules are intended to advance a provider’s ability to recognize, analyze, and improve quality improvement opportunities in their organization. In addition, IHI offers a comprehensive web-based training on the Model for Improvement, a tool for making rapid improvements in care.

Forming the Infection Control Team (ICT)
Infection Control Doctor (ICD) and Infection Control Nurse (ICN) are specialists in infection control. The ICT is a source of expert knowledge but the responsibility for
infection control should primarily lie with the clinical team. The ICT should be a multidisciplinary team.

To begin with, the members of the ICT should be given time and resources to develop necessary skills and orientation. There are sufficient information resources, most freely available and it should not be too difficult for the members to acquire necessary skills and understanding of the ‘improvement method’ within two to three months. The team will inevitably mature and continue to acquire new skills and develop new insight as they continue to confront practical problems on the ground. The authority must ensure that the team has its and senior doctors full support.

Membership of the ICT:
1. Director, a senior doctor who has a senior management role, is suitable for this position. Director is expected to provide the system leadership. This person must possess enough authority to institute a change that has been suggested and to overcome barriers that arise.

2. Infection Control Doctor and Microbiologist, who is expected to serve as a technical expert who knows the subject intimately and who understands the processes of care;

3. Lead Infection Prevention Control Nurse Specialist, who is expected to provide day-to-day leadership assuring that tasks are implemented and necessary data being collected;

4. Infection Prevention and Control Nurses (one assigned per project location/ward/department), who are expected to collect surveillance data and provide hand on training and advice to the frontline staff on a daily basis;

5. Antibiotic Specialist, a senior physician with interest and expertise, who can provide leadership to develop a hospital antibiotic policy and guidelines for the management of common HAI;

6. Team Administrator;
7. An expert on improvement methods (optional), who can provide additional technical support by helping the team determine what to measure, assisting in design of simple, effective measurement tools, and providing guidance on collection, interpretation, and display of data.

**Setting the aims**

The ICT must set a few clear and achievable aims at the outset. The aim should be time-specific and measurable; it should also define the specific population of patients that will be affected. For example, following two aims could be set which are measurable and time-specific in defined locations affecting a specific population:

1. Reduce the incidence of Surgical Site Infections (SSI) by 50% in 3 months in one general surgical wards of the hospital

2. Reduce the incidence of infections associated central venous access devices in intensive care unit (ICU) by 50% in 3 months

**Establishing measure (surveillance)**

‘There may be infection control without surveillance, but those who practice without measurement will be like crew of an orbiting ship travelling through space without instruments, unable to identify their current bearings, the probability of hazard, their direction or rate of travel’ – Richard Wenzel

Establishing rate of HCAIs via surveillance is necessary to determine the scale of the problem; therefore, resources necessary and appropriate strategy to address the situation, and demonstrate that an improvement is taking place (rate of HCAIs reducing) as a result of new intervention put in place. Establishing measure is the only way to show that changes made are actually leading to an improvement.\(^\text{32}\)
The surveillance strategies[^1]  

1. Targeted Outcome Surveillance: Initially for a limited period to establish the scale of the problem (e.g., endemic or baseline surgical site infection rate) in a given area or for a specific infection and then to check periodically to see if the infection control measures put in place are leading to improvement and, if not, explore why and how to address the situation. This strategy will serve the purpose without having to devote considerable resources otherwise necessary for outcome surveillance which aims to monitor occurrence of each incidence of HCAI. Once the capacity is established for a system of basic surveillance to identify any outbreak of HCAIs can be incorporated to this surveillance strategy.

2. Regular Process Surveillance (or audit): The aim being to observe/monitor infection control practices against a set standard such as compliance with hand hygiene or IV canula care. This process is continued with remedial measures instituted as and when necessary until the practice meets the recommended standard to complete the audit ‘loop’.

Selecting interventions

In regards to the two examples sited above following interventions should be adopted:

1. Start Hand hygiene campaign as per the WHO ‘Clean Care is Safer Care’[^6] initiative, essentially focussing on ‘5 Moments for Hand Hygiene’ approach which defines the key moments when health-care workers should perform hand hygiene and designed to be easy to learn, logical and applicable in a wide range of settings.

2. Implement a local central venous access ‘care bundle’ for ICU/ITU patients - this care bundle may be adapted from Guidelines for preventing infections associated with the

[^1]: The surveillance strategies
[^6]: ‘Clean Care is Safer Care’ and ‘Surgical Safety’ are components of the WHO international high profile ‘Patient Safety’ campaign (http://www.who.int/patientsafety/en).
use of central venous access devices or High Impact Intervention No 1: Central venous catheter care bundle.

3. Adopt the 'Surgical Safety’ checklist recommended by the WHO.

4. Implement a locally developed SSI prevention care bundle adapted from the following
   a. Getting Started Kit: Prevent Surgical Site Infections - How-to Guide
   b. High Impact Intervention No 4: Care bundle to prevent surgical site infection
   c. NICE Clinical Guideline 74: Preventing and treating surgical site infections

Testing changes

According to the principle of the Plan-Do-Study-Act (PDSA) cycle, the ICT will carry these interventions on a small scale in the specified locations viz., one surgical ward and the ICU/ITU and learn from the results and refine the changes if desired improvement is not achieved.

In regards to the two specific examples of aims set above, the whole strategy can be applied as follows:

1. Outcome surveillance for 1 month of Surgical Site Infections and Intra Venous Access Device associated infections in general surgery and ICU/ITU, respectively to establish the baseline.

2. Daily process surveillance (or audit) of interventions (e.g., hand hygiene, IV canula care, adherence to antimicrobial policy) throughout the project period recording compliance by the staff.

3. Repeat (1) after specific interventions have been in place for 3 months to ascertain if there is any improvement.

Implementing changes

Once successful on in these two locations in achieving improvements, the team can implement the changes on a broader scale perhaps few more wards.
Spreading changes

Eventually, the team can spread the changes to other parts of the organization or even in other organizations.

Routine functions of the ICT

In addition to driving specific improvement programmes, the ICT is expected to

1. provide advice to the staff to help them prevent and manage infection (individual patients or on clusters or suspected outbreak) including decontamination of equipment and environmental cleaning;
2. produce Guidelines on Prevention and Management of Infection;
3. provide Education and Training for all members of staff and
4. liaising with departments/agencies in purchasing and planning, including building and refurbishment work, to ensure infection-control issues are considered.

Expert input in infrastructure development and renovation project

There is a growing body of evidence suggesting links between built environment and quality of care. During new construction and renovation of healthcare environment, incorporation of plan to reduce risk of adverse outcome with emphasis on infection control and prevention is now a standard practice. Ideally infection control is ‘designed-in’ at the planning and design stages of a healthcare-facility, new-build or renovation, and that input continues up to the final build stage. Designed-in infection control means that designers, engineers, facilities managers and planners work in collaborative partnership with infection control experts to deliver facilities in which infection control needs have been planned for, anticipated and met.

Issues to be addressed pertinent to infection control include:

1. Storage and equipment cleaning areas
2. Hand-washing facilities
3. Furnishing and fittings
4. Appropriate finishes
5. Isolation rooms
6. Specific products with infection control implications

In general design should ensure that surfaces are easily accessible for cleaning, and that chlorine based cleaning agents will not affect the finish, it should also dry quickly.

All ongoing and planned renovation projects need to be reviewed to ensure that the specifications for infection control are met. It is essential that local design professionals are aware of development in this area and seek advice from infection control specialists.

**Improvement of the existing environment**

We recommend that existing built environment and facilities are urgently renovated and upgraded to make the following provisions:

**Provision of 24 hour running water**

Currently running water is available for 2 hours at a time 4 times a day. With multimillion rupees infrastructural developments currently going on, it is an urgent priority that provision for running water round the clock is made.

**Hand-washing clinical sinks**

Hand-washing is without doubt the most important intervention in the control of cross-infection. At present hand-washing facility is virtually non existent within the wards. This is an urgent priority that sufficient hand easily accessible wash basins with the following specifications placed appropriately are provisioned.

1. One basin suitably placed for each bay.
2. Taps in clinical areas should be of the elbow operated variety.
3. Hand-wash basins must not be obstructed.
4. There should be sufficient space around the basin to wall-mount alcohol gel, liquid soap, hand disinfectant and paper towels.

5. Soaps should not be refillable, but be of a disposable single-cartridge design.

6. Paper towels should be provided (wall mounted); use of cotton towel not recommended.

7. Foot operated pedal bins should be provided and situated by each clinical washbasin.

8. Waterproof splash backs should be fitted behind all sinks.

9. Should have curved sides with no plugs, have no overflows.

**Alcohol-based handrub**

Alcohol-based handrub for hand hygiene is an alternative to hand-washing with soap and water before and after patient contact. Alcohol-based handrub does not eliminate the requirement of hand-washing with soap and water by the doctors and nurses. Hand-washing is always required for a visibly dirty hand recommended after every 5 applications of alcohol-based handrub.

Immediate adoption of alcohol-based handrub by the hospital will improve hand hygiene standard and allow the authority some time to gradually increase the number of hand-washing clinical sinks within the clinical areas to the optimum in a planned way.

**Utility rooms**

Provisions should be made within the ward for the following ancillary areas:

**Dirty utility room**

Sufficient space and facilities for holding and reprocessing of bedpans, urinals and vomit bowls are required where patients are looked after.

Hand-wash facilities are necessary and separate sinks should be provided in areas where contaminated waste water or blood and body fluids are disposed of.
The sink provided for the domestic cleaners must be a low level one for easy emptying of buckets and the reduction of the risk of splashing.

There should be space for cleaning their equipment.

**Clean utility room**

Space/storage for sterile supplies, equipment and other clean supplies is needed. Storage should be in clean cupboards, not open racks where contamination with dust is more likely.

Floors must be cleaned easily and not impeded by inappropriate storage on the floor of boxes of over-stocked items.

Stock rotation is essential to ensure that sterile items do not go out of date.

Surfaces must be kept free of clutter to enable frequent cleaning of work surfaces.

**Furnishing and fittings**

Hard flooring: Floors should be smooth, easily cleaned, and appropriately wear resistant.

There should be coving between the floor and the wall to prevent accumulation of dust and dirt in corners and crevices.

Finishes: Materials and finishes should be selected to minimise maintenance, they should be compatible with the rooms intended function. All finishes in clinical areas should be chosen with cleaning in mind, especially where contamination with blood or body fluids is a possibility.

Walls: Smooth paint surfaces are easier to clean.

Ceilings: Should be easily accessible for cleaning and preferably with a wipeable smooth surface.

Doors: All bays and side rooms need doors if they are to be used for cohort barrier nursing or isolation nursing.
Curtains and blinds: Curtains are easily contaminated, for good infection control it is important that policies are in place for regular laundering and they can withstand washing at disinfection temperatures. Venetian blinds are not recommended, as they are extremely difficult to clean. A spare set of curtains is required.

Soft furnishings: These are easily contaminated, and may become malodorous, so they should be covered in a material that is impermeable to fluids, or of the vinyl variety that is wipeable and not affected by chlorine based cleaning solutions.

Work surfaces: Should be designed for ease of cleaning. Surfaces near plumbing fixtures should be smooth, non-porous and water resistant. They should be free of cracks, fissures, open joints and crevices that will retain or permit the passage of dirt and particles.

All joints must be sealed. Keep work surfaces clear, not as storage areas.

Touch surfaces: Door handles and plates, grab rails and light switches are important potential vectors for the spread of infection. New technologies and research suggest that copper/copper alloy fittings reduce bacterial survival times and can be cost-effective.

Isolation rooms

Isolation rooms for infected patients are essential to prevent cross-transmission. The current ward layout should be reconfigured to create at least 2 isolation rooms per ward. If this is not feasible, consideration must be given to build a block of cohort isolation wards/rooms to nurse infectious patients.

Theatre complex renovation

It is understood that more that INR 30 million has been allocated for existing theatre renovation. We strongly recommend that expert advice is taken and technical literature is consulted to ensure that the theatre complex is renovated to acceptable standard ensuring safe surgery and low rate of SSI ([Figure 25, Figure 26, Figure 27, Figure 28). The SSI rate generally depends on factors such as the type of surgery, the cleanliness of equipment,
medical procedures, and the level of microorganisms in the immediate and surrounding environments. Another major factor to consider is the quality of the air in the operating room. At present the operation theatre is not equipped with mechanical plenum ventilation system and depends on natural ventilation. Even if it is not immediately feasible to install a mechanical ventilation system (Figure 29), a number of measures can be taken including improving the theatre condition and ensuring theatre discipline, adoption of the WHO Surgical Safety checklist and a rational antibiotic prophylaxis policy to compensate for lower than optimal air quality.
Operating theatre suite

Figure 25 Operating theatre suit-1 (reproduced from 294)
Operating theatre suite

Typical operating theatre suite with integral scrub room

Sheet 2

Figure 26 Operating theatre suit-2 (reproduced from 294)
Operating theatre suite

Typical operating theatre suite with integral scrub room

Key to operating theatre

1. Theatre control panel
2. Infection control monitor
3. Scrub station
4. Vascular dressing trolleys (x 2) and hanging trolleys for equipment, for example spine, radiology equipment and cautery machine
5. Disinfectant, swab stock, suction unit
6. Operating microscope

For key to other rooms see

Anaesthetic room - Sheet 4
Preparation room and dirty utility - Sheet 4
Scrub room - Sheet 4

Figure 27 Operating theatre suit-3 (reproduced from 294)
Shared scrub room

Two theatre suites sharing combined scrub room

Sheet 4

Key for scrub room

1. A zone of 800 mm wide by 900 mm deep is required for washing hands and forearms in front of each scrub tap.

2. Non-touch scrub taps are recommended.

3. Shared non-touch scrub solution dispensers located in a 200 mm zone between each tap.
   - For the height of the scrub trough and water outlets, see HTM 64 - 'Sanitary assemblies'.
   - Liquid soap and nail brush dispensers should be 1100–1200 mm above finished floor level.

4. Disposable glove, apron and mask dispenser.

5. 1200 mm clear space is required for arms in extended position during gowning procedure, with an additional 300 mm minimum side clearance to prevent contamination.

6. Shelf space is required for storage of gown packs. These should be sited conveniently but not above gowning trolley.

7. Sufficient space should be provided around gowning trolley to permit safe opening of the gown pack.

8. Radio-controlled clock with sweep seconds hand.

All anaesthetic rooms should be identical and under no circumstances can they be handed/mirrored.

For key to other rooms see:
- Anaesthetic room - Sheet 1
- Preparation room and dirty utility - Sheet 2
- Operating theatre - Sheet 3

Figure 28 Operating theatre suit-4 (reproduced from 294)
Provision of sterile supplies

There was no CSSD at the time of inspection in the hospital which was an urgent requirement. The sterilization of wrapped items and hollow instruments for surgery are currently carried out in a room within the operation theatre complex. It is a matter of serious concern that there was no robust quality control system in place to ensure decontamination cycle validation (Figure 30).
Moreover, steam sterilizers need to be commissioned on installation or tested at appropriate intervals as recommended in a number of technical publications.

Figure 31 SSD layout: double-door steriliser configuration (reproduced from 354)

The layout of the area is also not suitable for the purpose (Figure 31, Figure 32). It is very likely that even the critical items are not effectively sterilized putting patients at great risk.

It is necessary that the proposal for the CSSD is produced after due consideration of
technical literature\textsuperscript{354} with consultation with expert. It is advisable that senior members of the sterilization team visit CCSD of a national level hospital for training.

\begin{figure}[h]
\centering
\includegraphics[width=\textwidth]{figure32.png}
\caption{SSD layout: single-door steriliser configuration (reproduced from \textsuperscript{354})}
\end{figure}
Local reprocessing

Water bath currently in use to sterilize solid instrument in the nurses’ station should immediately be removed and replaced by Benchtop downward displacement steam autoclaves suitable for the sterilization of solid instruments and utensils for immediate ward use. It should be noted that wrapped items and hollow instruments cannot be processed by these autoclaves. Benchtop autoclave with vacuum technology that allows sterilizing hollow instruments and wrapped items are available but these items are best sterilized in the CSSD.

GI endoscope decontamination

It is strongly recommend that number Endoscopy procedures carried out is planned and limited to a manageable numbers that allows required cleaning and disinfection time in between the procedures. An automated washer-disinfector is desirable but is not essential. Manual cleaning and disinfection is acceptable if the recommended process (cleaning → rinsing → disinfection → rinsing → drying → storage) is followed. We recommend that a local protocol is developed based World Gastroenterology Organisation’s Practice Guideline on Endoscope Disinfection355.

Special campaigns

Prevent Antimicrobial Resistance

Prevention of antimicrobial resistance in healthcare setting centres on four main strategies: prevent infection, diagnose and treat infection, use antimicrobials wisely, and prevent transmission. The hospital should embark on programmes targeting clinicians encouraging them to develop practice guidelines to prevent and effectively treat HCAIs. Educational resources and campaign material are available from sources like CDC (http://www.cdc.gov/drugresistance/healthcare/default.htm).
Essential components of preventing antibiotic resistance programme are graphically represented in Figure 33.

**Promotion of Hand Hygiene**

"Clean Care is Safer Care": The First Global Patient Safety Challenge

It is strongly recommended that the hospital as a matter of urgent priority adopt the WHO sponsored ‘Clean Care is Safer Care’ campaign. In fact, India has committed to address the Health Care associated infection in the country on 14 July, 2006 and support WHO sponsored initiatives to help countries tackle the menace of HAI\(^{356}\).

‘Clean Care is Safer Care’ addresses an issue of universal relevance to patient safety - action to reduce health care-associated infections (HAI) worldwide. The main plank of the campaign is ‘Five Moments for Hand Hygiene’ approach\(^{357}\). A range of tools and resources have been developed to complement the Five Moments approach including localised country specific tool. The material developed for Bangladesh\(^{358}\) in Bengali can be easily adapted in Assamese (Figure 34, 35, and 36)\(^{359, 360, 361}\).
Alcohol-based hand-rubs

‘Five Moments for Hand Hygiene’ put a great emphasis on alcohol-based hand-rubs. Proper use of alcohol-based hand-rubs renders the hands safe in terms of transmission of pathogens, and which can be used at the very place where pathogens are transmitted.
Figure 35 Hand-hygiene (alcohol rub) technique poster (example in Bengali)

At the present time, the most efficacious, well-tolerated and well-researched product which can be placed ergonomically and safely at the point of care is an alcohol-based handrub. It is unlikely, although not impossible, that running water, soap and towels will be installed right next to each patient's bed, or be available at the point of care in an affordable and practical way. In countries where access to sinks is limited or non-existent, alcohol-based
hand-rubs offer a method of preventing cross-infection which can be implemented in the short-term alongside a longer term strategy of sink installation\textsuperscript{362}. It has revolutionised hand hygiene improvement strategies in the modern age\textsuperscript{8}.

Figure 36 Hand-hygiene (soap & water) technique poster (example in Bengali)

\textsuperscript{8} Hands need to be washed with soap and water when they are visibly dirty or when exposure to potential spore-forming organisms is suspected or proven, or after using the lavatory. There is always need for healthcare staff to clean their hands with soap and water at certain times.
Making Alcohol-based hand-rubs available at affordable cost

The recommended WHO formulations meet both US and European norms. The formulation is useful for those facilities which at present do not have access to commercially available alcohol-based handrub due to logistics or high cost, or would prefer to undertake local production instead of procurement from the market. Locally marketed commercially available alcohol-based handrub products are prohibitively expensive for large scale consumption. It is suggested that the formula is manufactured within the health-care facility, with a pharmacy laboratory on-site. Alternatively, local companies with the correct facilities can be provided with contract to manufacture the WHO formula on behalf of the hospital, this will save a huge amount of public money and ensure steady supply.

Other strategic initiatives

Reducing bed occupancy

A crowded ward exerts heavy pressure on the staff and provides increased opportunities for cross-transmission of nosocomial pathogens, particularly when, as in this hospital, bed occupancy is almost 100% and patient to nurses staffing ratio is well under what would be considered as acceptable.

We witnessed unit with over 100% bed-occupancy (extra beds provisioned on the floor) whereas the adjacent unit had free beds.

It is virtually impossible to render good care if bed-occupancy is at such a high level. Ideally, the current 8 bedded-bays should accommodate only 6 beds given the bed-space requirement between the beds for safe clinical care.

While flow of patients to the hospital in not under control of the hospital authority as healthcare system in the peripheral and interior areas of the state is yet to develop
sufficient capacity, we still feel that there is an urgent need look into the bed-management and patient admission/discharge strategy to increase the efficiency of the system so that, at the least, no provision for extra beds on the floor has to be made.

We calculated that average length of inpatient stay last year was 12 days. We have found that significant number of patients are well enough to be discharged but waiting for certain investigations, particularly imaging, to be completed.

We feel that whole patient journey from admission to discharge can be streamlined allowing discharge at the earliest opportunity. Inpatient admission criteria should be established. It might also be possible more patients to be managed as outdoor by extending the hours allowing examination, investigations and treatment to be done on the same day.

We suggest that a team is assembled to establish the facts, and try on a small scale involving a few wards certain changes (admission criteria, co-ordination with X-ray and imaging, safe early discharge criteria) with an aim to reduce bed occupancy by at least 25% so that at any times there are no more than 6 patients on an 8 bedded bay.

The necessary changes required will be based on a review of the current situations:

Is there a formal admission policy? Are there any admissions that can actually be managed safely as outpatient? Or early discharge with outpatient follow up, at least for the local patients, would be clinically appropriate?

Is there any variation in admission practice depending on the consultant? If so, can any good practice be identified that can form basis of a new admission policy?

Is there any delays in discharge because of investigations are not complete? Can there be any way of co-ordinating with the laboratory and radiology department to prioritise investigations for patients who are ready for discharge?

Is there any delay due to reasons other than clinical?
A detail review of the current practice would help identifying changes required to reduce the bed occupancy which can then be tried on a small scale (PDSA cycle) and eventually rolled out widely to other wards.

Visitors, Attendants and Relatives

The hospital is overcrowded with patient's visitors, relatives and attendants, which is not ideal for infection control.

The hospital needs a formal patient's 'visitor, attendant and relative' policy clearly stating out visiting hours, and role and responsibility of the relative and attendant in patient's care.

Enforcing such a policy with access barrier may be possible but may be better addressed by promoting an understanding amongst public - information leaflets, adequately staffed reception at the main outdoor that satisfies relevant information need of the visitors and attendants are way forward. Moreover, adequate service provision (canteen, toilet, rest area) for the visitors and attendants may make a positive impact.

In summary, a formal 'improvement initiative' should be launched based on the 'model of improvement' approach discussed above.